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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,084	06/15/2007	Paul J. Keall	02940350AA	3890

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EXAMINER
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HOFFA, ANGELA MARIE

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,084	<b>Applicant(s)</b> KEALL ET AL.	
	<b>Examiner</b> ANGELA M. HOFFA	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 1,2,4-7,9-12,14 and 15 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☒ Claim(s) 1,2,4 and 5 is/are allowed.
- 7) ☒ Claim(s) 6,7,9-12,14 and 15 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 20 October 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 3, 2010 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-12 and 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 11, the limitation of "controlling post-processing of a 4D CT scan of said anatomy so as *to omit data* acquired during periods having said detected out of tolerance condition" is not understood. From what is the data being omitted? (i.e. a reconstructed image?)

Regarding Claim 14, the limitation of "adapting said 4D CT scan to said respiratory signal by excluding during said post-processing of said 4D CT scan data acquired..." is not understood. How can the 4D CT scan be adapted during post-processing if the scan is already completed?

Further regarding Claim 14, it is not understood what the data is being excluded from. (i.e. post-processing to form a reconstructed image?)

Regarding Claim 15, the limitation "data acquired during irregular respiratory cycles" lacks antecedent basis.

Further regarding Claim 15, it is not understood how data can be omitted from the 4D CT scan if the scan is already completed, as required by the claim in the limitation of "data...is excluded by omitting data". Further, from what is data being omitted (i.e. a reconstructed image)?

4. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

5. Regarding Claims 6-7 and 9-10, Applicant is requested to clarify on the record whether or not 112, 6<sup>th</sup> means plus function language is being invoked.

For the purposes of examination, Claims 6-7 and 9-10 meet the provisions of 112, 6<sup>th</sup> paragraph.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may amend the claim so that it will clearly not invoke 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 6-7 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,959,266 to Mostafavi (of record).

Regarding Claim 6, Mostafavi discloses a system for reducing motion artifacts and patient dose in radiological imaging using four dimensional computed tomography (4D CT), comprising:

means for identifying a pattern in an average cycle of an anatomy being imaged, said pattern being responsive to a reproducible periodic motion of said anatomy learned through training of the patient (Mostafavi uses a correlation algorithm, difference function, or a model of physiological signal to identify the pattern, col. 6, line 64 – col. 7, line 28, 502, 504, fig. 5; this is considered an acceptable equivalent to the claimed training function for meeting the requirements of 112, 6<sup>th</sup> paragraph);

means for establishing spatial and temporal tolerances around said pattern, said tolerances being based on data of said periodic motion learned through training of the patient and forming an envelope around said pattern balancing an acquisition time

Art Unit: 3768

against a quality of an acquired 4D CT image (degree and point of match within range? 504, 508, 509, fig. 5);

means for measuring a period motion of said anatomy so as to detect when said periodic motion is outside said tolerances (passive markers 114, fig. 1);

means for controlling a 4D CT scan of said anatomy so as to pause the scan during periods having said detected out of tolerance condition (computer 110, fig. 1 gates the scan based on the deviation detected in fig. 5).

Regarding Claim 7, Mostafavi further teaches wherein said anatomy is a lung and said measuring means uses a respiratory signal (fig. 3).

Regarding Claim 9, Mostafavi further teaches wherein said controlling step further comprises:

means for acquiring a respiratory signal during said 4D CT scan;

means for applying said envelope to said respiratory signal; and

means for adapting said 4D CT scan to said respiratory signal by excluding from said 4D CT scan data acquired when said respiratory signal is not within said envelope (the computer controls the functions displayed in fig. 3).

Regarding Claim 10, Mostafavi further teaches wherein said adapting means provides that data acquired during irregular respiratory cycles is excluded by pausing said 4D CT scan data acquisition when said respiratory signal is not within said envelope (300, fig. 3).

### ***Response to Arguments***

8. Applicant's arguments, filed May 3, 1010, with respect to the rejection(s) of claim(s) 1-2, 4-5, 11-12, and 14-15 under 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly applied reference for claims 6-7 and 9-10.

***Allowable Subject Matter***

9. Claims 1-2 and 4-5 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest training a patient to reproduce a pattern of periodic motion of an anatomy and identifying spatial and temporal tolerances from the pattern in order to measure the period motion during a 4D CT scan and pause the scan during periods outside the tolerances, as recited in Claim 1. Applicant discloses that the use of training "significantly improves respiratory reproducibility" (page 7, lines 25-28).

Exemplary prior art US Patent No. 6,959,266 to Mostafavi discloses a method for reducing motion artifacts and patient dose in radiological imaging using 4D CT but does not use patient training to identify the pattern. Instead, Mostafavi relies upon correlation algorithms, difference functions, or models of physiological signal to identify the pattern (col. 6, line 64 – col. 7, line 28, 502, 504, fig. 5). Mostafavi provides adaptive techniques in identifying tolerances used to exclude the artifacts from the image data series. Applicant does not use adaptive tolerances.

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,298,260 and 6,076,005 to Sontag disclose detecting training data while a patient breathes normally but the patient is not trained. US 2004/0082853 to Sasaki, US 7769430 to Mostafavi, US 7720518 to Motomura, US 7393329 to Wong, and US 7182083 to Yanof disclose giving the patient instructions or training to hold breathes or direct breathing during an imaging scan but a tolerance model is not determined based on trained breathing before the imaging scan. NPL document George et al discloses the effects and benefits of audiovisual biofeedback in respiratory-gated radiotherapy but does not qualify as prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA M. HOFFA whose telephone number is (571)270-7408. The examiner can normally be reached on Monday - Friday, 10:00 am - 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3768

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M. H./  
Examiner, Art Unit 3768

/Tse Chen/

Supervisory Patent Examiner, Art Unit 3777